Pre-contoured vs contoured rod implants in adolescent idiopathic scoliosis surgery – a retrospective single centre analysis

Sean C. Glossop[1], Munyaradzi Muyengwa[2], Michael J. McCarthy[2]*

1. School of Medicine, Cardiff University
2. Department of Spinal Surgery, University Hospital of Wales, Cardiff

*Senior Author

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Abstract

Introduction: Adolescent idiopathic scoliosis (AIS) is one of the most common forms of scoliosis. Various manufactured implant kits are available to surgeons, with one of the main variables being whether correctional rods are pre-contoured by the manufacturer or manually contoured by the surgeon in theatre. This study aimed to assess whether pre-contoured vs contoured rods have an impact on operative outcomes.

Methods: Bluespier software was used to develop a database of routinely collected information, for all spinal operations conducted between January 2013 and December 2023. This data was filtered in accordance with the inclusion criteria and analysed. We included patients between the ages of 10 to 18 at the time of operation, diagnosed with AIS. Data collected included the type of implant, demographic information, and Cobb angles.

Results: 265 patients were identified as being eligible in accordance with the inclusion criteria. 8.7% (n=23) required revision surgery. Data for implant kits used was available for 96.2% of these cases (n=255). Cobb angle decrease was calculated using pre- and post-operative data, showing no statistically significant mean reduction in cobb angle decrease between patients who had pre-contoured rods vs contoured rods (p=0.290).

Conclusions: Pre-contoured patient specific rods appear to have no significant affect on improvement of Cobb angles for AIS. This finding is useful to stakeholders worldwide, with factors such as cost burden and operative time of either being points for consideration when deciding which to use alongside holistic patient assessment.

Introduction

Scoliosis is a general term used to describe an abnormal curvature of the spine, and it can be broadly categorised into either idiopathic, congenital, or neuromuscular[1]. The most common of these is idiopathic scoliosis[2], which can be further classified by age group; infantile, juvenile, or adolescent. Due to the nature of its unknown aetiology, idiopathic scoliosis is normally a diagnosis of exclusion, where other causes of scoliosis have been ruled out[3].

Adolescent idiopathic scoliosis (AIS) refers specifically to idiopathic scoliosis arising between the ages of 10 to 18 that cannot be attributed to a particular cause and can be a particularly concerning diagnosis for both the patient and their relatives[4]. The condition may be managed conservatively, either through observation or orthotic braces, however in certain cases surgery may be beneficial to reduce the spinal deformity[5].

Surgery for correcting AIS commonly involves posterior spinal fusion with instrumentation in which metal screws are inserted into the vertebral pedicles, rods subsequently attached, and correctional force applied to correct the scoliotic curve, although minimally invasive approaches have been described in recent literature[6-8]. Whilst severe intraoperative and post-operative complications are uncommon[9], certain patients may require revision surgery.

Correctional rod implants used in AIS surgery can either be pre-contoured by the manufacturer according to patient specific parameters, a relatively novel invention also known as “patient specific rods”, or they can be contoured by the surgeon in the operating room using a specialised device. The literature relating to whether use of either is superior is currently limited[10], with one study reporting on the topic in adult spinal deformities[11]. Additionally, certain studies have focused on rod thickness/material[12, 13] and others have researched in the context of sagittal or coronal alignment[14].

The aim of this study was to analyse and compare the two types of rods, pre-contoured and contoured, with relation to operative outcomes.

Methods

This study involved the use of retrospective data routinely recorded over a 10-year period, between January 2013 and December 2023, at a UK tertiary care hospital with a dedicated spinal surgery department.

Ethical approval was not required as this data was gathered for departmental quality improvement purposes.

A database was formed for all spinal operations carried out during this period at the hospital using Bluespier software. Duplicates were removed from the dataset manually so that only patients who met the inclusion criteria were included. This database was then filtered to meet the agreed inclusion criteria (Table 1), with anonymised information subsequently placed in a Microsoft® Excel® (version 1808) spreadsheet for analysis.

Synapse 5 radiology software was also used to view pre- and post-operative imaging. Cobb angles and coronal alignment were calculated from whole spine x-rays. Where patients had two curves, the major curve was used for calculation, and for all Cobb angles, pre- and post-op x-rays were used to calculate exact measurements from the same spinal levels.

CRITERIA	INCLUSION	EXCLUSION
Research participant	Patients diagnosed with idiopathic adolescent scoliosis	Patients with scoliosis related to other causes such as congenital or neuromuscular
Age (at time of procedure)	Patients between the ages of 10 to 18	Patients younger than 10 or older than 18
Timescale	January 2013 to December 2023 (10-year period)	Any operations carried out before or after this period
Operative methods	Anterior and posterior instrumentation methods	N/A

Table 1: *The inclusion and exclusion criteria used for this study*

Data points recorded for each patient in the spreadsheet were broadly categorised into the following: demographics, pre-operative data, intra-operative data, and post-operative data. Each of these categories involved multiple column names, including but not limited to past medical history, dates of referrals and imaging, pre- and post-operative cobb angles, type of implant/screws used, number of screws and location of screws.

Type of implant kit was classified as either pre-contoured or contoured using binary code based on clinical knowledge of the kit manufacturer and the year of surgery.

Statistical analysis was undertaken using IBM® SPSS® (version 29).

Results

Demographics

A total of 265 patients were included, 85.3% were female (n=226) and 14.7% male (n=39).

All patients had been given a confirmed diagnosis of Adolescent Idiopathic Scoliosis and were aged between 11 and 18 at the time of surgery, with a mean age of 14.6 years.

The mean average stay in hospital from day of surgery to discharge was 6.96 days (s.d. 3.37), with a range of 4 to 38 days.

Cobb angles

The mean average for pre-operative Cobb angles was 68.12 (s.d. 17.84) and ranged from 22 to 128. The mean average for post operative Cobb angles was 32.04 (s.d. 12.30), ranging from 6 to 86.

A paired t-test of the means showed that the mean post-operative Cobb angles for all 265 patients was significantly lower than the mean pre-operative Cobb angles ($p < 0.001$).

There was no significant difference in mean decrease in Cobb angles between males and females ($p=0.501$) following surgical intervention (independent sample t-test).

Data was unavailable for type of implant for 10 patients, reducing the sample size to 255 patients for comparison of Cobb angles with pre-contoured and contoured rod use. 139 of these patients had pre-contoured rod implants, and 116 had contoured rods.

The mean Cobb angle reduction following surgery for the pre-contoured rod patients was 36.91, while the mean difference for the contoured rod group was 35.32. These means were tested using an independent sample t-test which showed no significant difference in Cobb angle decrease when either rod was used ($p=0.290$).

A multivariate analysis of variance (MANOVA) test also showed no significant difference when pre- and post-operative Cobb angles were tested against the fixed independent variable (pre-contoured vs contoured rods) ($p=0.547$).

Rate of surgical revision: pre-contoured vs contoured rods

Of the 265 patients, 8.7% (n=23) were required to return to theatre for revision surgery. 11 of these had contoured rod implants and 12 had pre-contoured rods implants.

Operative time (to be completed after submission)

Data for operative time was available for patients from 2018 onwards, allowing comparison of operative time for pre-contoured rod implants vs contoured rod implants for X patients.

Discussion

The results of this study provide a platform for interesting discussion, in that pre-contoured vs contoured rod use does not appear to affect gross operative outcomes of AIS surgery when measured against Cobb angle decrease, with both groups appearing to have largely similar mean decreases of no statistical significance. However, this is indeed a significant finding itself, posing a rhetoric of multiple factors for discussion.

In the case of this study, 8.7% (n=23) of patients had to return to theatre for a revision surgery. This is a relatively reasonable figure at our tertiary care centre, considering other studies reporting percentages between 13.1% and 19%[15, 16]. However, due to the design of our study which included patients up until the year 2023, our revision rate may be slightly lower since there has been no long term follow up data available for certain cases. Revision reasons for AIS can vary significantly, from neurological issues to respiratory and cardiac problems amongst many others[17].

Cost burden of pre-contoured rods and contoured rods may also be relevant to the findings of this study. Whilst there are surgical uses for either, procurement cost may be a factor in certain health services across the world, particularly considering our study which has demonstrated that both have a similar effect in reduction of scoliotic curves based upon Cobb angles. However interestingly, one study showed that reducing length of hospital stay contributed to the greatest decrease in costs compared to intraoperative variables[18].

Rod material and thickness for scoliosis implants may also have a level of significance relating to pre-contoured and manually contoured rods, with one laboratory-based study showing that 6mm pre-contoured rods required a significantly lower corrective force compared to 6mm manually contoured rods[19]. In our study, data relating to rod thickness and material was difficult to obtain, with most intraoperative Bluespier notes not stating these details, however this leaves the topic open to exploration in future research.

Similarly, another consideration may be operative time, a topic that appears limited in the current literature in the context of whether pre-contoured rods are quicker to operate with than contoured rods or vice versa. Patient specific rods have been addressed in adult spinal surgery and have shown to improve operative time[20], although this has not currently been reported on in paediatric scoliosis cases. Pre-contoured rods may have the potential to reduce intraoperative time due to the nature of the surgeon not having to contour them for the patient during the surgery, and future studies should aim to assess this.

In terms of operative benefits of pre-contoured patient specific rods, most studies have been conducted on cohorts with adult spinal deformities, however these have the potential to be transferable for paediatric surgery which should be a point of focus for future research. One study by Faulks *et al.* (2023)[11] that focused on patient specific rod surgery in adult spinal deformity, with an average cohort age of 71.9, showed them to reduce proximal junctional failure.

Finally, the limitations of this study were its retrospective design and that data had to be pulled from various databases whilst being matched with the correct patients. This may have allowed cases to be missed or mixed when manually utilising spreadsheets, despite the stringent effort to prevent this. Therefore, there was potential for misclassification bias and selection bias.

Conclusions

In summary, the use of pre-contoured and contoured rods does not appear to affect scoliotic Cobb angle improvement following surgical intervention, with both types of implants showing consistent and similar Cobb angle decreases after surgery for AIS. These findings may be important in countries around the world when considering cost of either implant alongside holistic patient assessment, as well as balancing this with operating time and rates of revision. Further studies should aim to assess related factors to pre-contoured vs contoured rod implant use in AIS surgery such as intraoperative time, rod breakages and post-operative complications in order to satisfactorily assess whether there are benefits to using either.

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